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DUR DIGEST

The Bulletin of Medicaid Drug Utilization Review (DUR) in Ohio FFS

Introduction to Change Healthcare

Change Healthcare is the pharmacy benefit administrator for the Ohio Department of Medicaid (ODM). Our role is to manage and coordinate the Ohio Medicaid Fee-for-Service (FFS) claims processing and prior authorization determination activity. Change Healthcare is also delegated to administer the Retrospective Drug Utilization Review (DUR) program for the Ohio Medicaid FFS population.

Keppra (Levetiracetam) Above 3,000 Milligrams (mg) Per Day[1]

Purpose

The manufacturer recommended dose of levetiracetam is 3,000mg/day and 60 mg/kg/day in adults and pediatric patients, respectively. Prescribers are being asked to provide a diagnosis code and clinical rationale for exceeding this dose.

Intervention Criteria

Members exceeding 3,000mg/day of levetiracetam were identified using pharmacy claim data. Calls were made to prescribers to obtain rationale for using higher doses, but the response was minimal.

Intervention Goals

The goal of this intervention is to gather clinical information from prescribers whose patients are utilizing levetiracetam above the manufacturers recommended dose. The information provided will help ODM determine if quantity limits should be placed on levetiracetam pharmacy claims. Doses exceeding these quantity limits would require prior authorization.

Background and Standards of Clinical Practice

According to the package insert of levetiracetam, increasing dosages have not been correlated with an increased response to the medication. The maximum recommended dosage of levetiracetam is 60mg/kg/day for children and 3,000mg/day for adults.

Ohio Department of Medicaid Fee for Service Preferred Drug List (PDL)

Central Nervous System (CNS) Agents: Anticonvulsants

LENGTH OF AUTHORIZATIONS: 1 year

GRANDFATHERING:
Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
   - Allergy to two preferred medications
   - Contraindication to or drug interaction with two preferred medications
   - History of unacceptable/toxic side effects to two preferred medications
   - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
2. If there has been a therapeutic failure to no less than two preferred products for a one-month trial each. Prescriptions submitted with the prescriber NPI of a physician who has registered a neurology specialty with Ohio Medicaid, for products that are used only for seizures, require a trial of one preferred product for one month. This provision applies only to the standard tablet/capsule dosage form, and does not apply to brand products with available generic alternatives.

ANTICONVULSANTS: FIRST GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CLONAZEPAM tablet (generic of Klonopin®)	CELONTIN® (methsuximide)
DIASTAT® rectal gel (diazepam)	CLONAZEPAM ODT (generic of Klonopin® wafer)
DIVALPROEX (generic of Depakote®)	DIAZEPAM rectal gel (generic of Diastat®)
DIVALPROEX ER (generic of Depakote® ER)	ONFI® (clobazam)
ETHOSUXAMIDE (generic of Zarontin®)	PEGANONE® (ethotoin)
PHENOBARBITAL	STAVZOR® (valproic acid delayed-release)
PHENYTOIN (generic of Dilantin®)	
PRIMIDONE (generic of Mysoline®)	
VALPROIC ACID (generic of Depakene®)	

ANTICONVULSANTS: SECOND GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GABAPENTIN (generic of Neurontin®)	BANZEL® (rufinamide)
LAMOTRIGINE IR tablet, chewable tablet (generic of Lamictal®)	BRIVIACT® (brivaracetam)
LEVETIRACETAM IR tablet, solution (generic of Keppra®)	FELBAMATE (generic of Felbatol®)
SABRIL® powder (no PA for age < 2)	FYCOMPA® (perampanel)
TOPIRAMATE tablet (generic of Topamax®)	LAMICTAL® ODT (lamotrigine)
ZONISAMIDE (generic of Zonegran®)	LAMOTRIGINE ER tablet (generic of Lamictal® XR)
	LEVETIRACETAM ER tablet (generic of Keppra® XR)
	LYRICA® (pregabalin)
	QUDEXY XR® (topiramate ER)
	SABRIL® powder (PA required for age > 2)
	SABRIL® tablet (vigabatrin)
	SPRITAM® (levetiracetam tablet for suspension)
	TIAGABINE (generic of Gabitril®)
	TOPIRAMATE ER
	TOPIRAMATE sprinkle cap (generic of Topamax® sprinkle cap)
	TROKENDI XR® (topiramate)

Long Term Use of Muscle Relaxants [2]

Purpose
Evidence shows treatment with skeletal muscle relaxants should be limited to two to three weeks. Common side effects for these medications include drowsiness, dizziness and dry mouth.[3]

Intervention Criteria
Members taking muscle relaxants for 90 days or greater. Members were identified using pharmacy claims.

Intervention Goals
The goal of this intervention is to make prescribers aware that muscle relaxants are not indicated for long-term use and to ensure appropriate treatment options are being used.

Background and Standards of Clinical Practice
Skeletal muscle relaxants are indicated for short-term use; therefore, multiple modalities including nonpharmacological methods may be warranted to prevent chronic use of these medications.

Nonpharmacological Treatment[4]

- Motor control exercise
- Heat
- Massage
- Physical therapy
- Acupuncture
- Spinal manipulation
- Mindfulness-based stress reduction
- Yoga
- Progressive relaxation

Ohio Department of Medicaid Fee for Service PDL

Central Nervous System (CNS) Agents: Skeletal Muscle Relaxants, Non-Benzodiazepine

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to an agent not requiring prior approval, then may approve the requested medication.

CNS AGENTS: SKELETAL MUSCLE RELAXANTS - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BACLOFEN (generic of Lioresal®)	CARISOPRODOL (generic of Soma®) *
CHLORZOXAZONE (generic of Parafon Forte®)	CARISOPRODOL COMPOUND (generic of Soma Compound®) *
CYCLOBENZAPRINE (generic of Flexeril®)	CARISOPRODOL COMPOUND W/CODEINE (generic of Soma Compound w/Codeine®) *
DANTROLENE (generic of Dantrium®)	CYCLOBENZAPRINE ER (generic of Amrix®)
METHOCARBAMOL (generic of Robaxin®)	FEXMID® (cyclobenzaprine)
TIZANIDINE tablets (generic of Zanaflex®)	LORZONE® (chlorzoxazone)
	METAXALONE (generic of Skelaxin®)
	ORPHENADRINE (generic of Norflex®)
	ORPHENADRINE COMPOUND (generic of Norgesic®)
	ORPHENADRINE COMPOUND FORTE (generic of Norgesic Forte®)
	TIZANIDINE capsules (generic of Zanaflex®)

* Note: Clinical criteria must be met for Soma®/Carisoprodol products– approvable only if no other muscle relaxant or agent to treat fibromyalgia, or any musculoskeletal condition, would serve the clinical needs of the patient.

FDA Drug Safety Communication[5]

July 10, 2018 The U.S. Food and Drug Administration (FDA) is strengthening the current warnings that fluoroquinolone antibiotics may cause 1) significant decreases in blood sugar and 2) increases in certain mental health side effects. Low blood sugar levels may result in serious problems, including coma, particularly in older people and patients with diabetes who are taking medications to reduce blood sugar.

Across the fluoroquinolone antibiotic class, a range of mental health side effects are already described under *Central Nervous System Effects* in the *Warnings and Precautions* section of the drug label, which differed by individual drug. The new label changes will make the mental health side effects more prominent and consistent across the fluoroquinolone drug class. The mental health side effects to be added or updated across all fluoroquinolones include: disturbances in attention, disorientation, agitation, nervousness, memory impairment, and delirium.

References

1. Keppra (levetiracetam) [package insert]. Smyrna: UCB, Inc., GA; 2009.
2. Ginzburg R. Choosing a Skeletal Muscle Relaxant. Am Fam Physician. 2008; 78:365-70.
3. Long Term Use of Cyclobenzaprine for Pain: A review of the Clinical Effectiveness. Available at: https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072822. Accessed July 26, 2018.
4. Qaseem A, Wilt TJ, McLean RM, Forciea MA; Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians. Ann Intern Med. 2017;166(7):514-530.
5. Food and Drug Administration. 2018 Drug Safety Communications. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm611032.htm. Accessed July 27, 2018.

Ohio Department of Medicaid
John R. Kasich, Governor
Barbara R. Sears, Director

Preferred Drug List (PDL) Changes
P&T Meeting Date: July 11, 2018
PDL Changes Effective Date: October 1, 2018

NEW PREFERRED DRUGS	
THERAPEUTIC CLASS	**PREFERRED STATUS**
Central Nervous System (CNS) Agents: Parkinson's Agents	amantadine
Infectious Disease Agents: Antivirals -HIV	Biktarvy® (bictegravir, emtricitabine, tenofovir alafenamide fumarate) Symfi Lo™ (efavirenz, lamivudine, tenofovir disoproxil fumarate)
Ophthalmic Agents: Glaucoma Agents	Rhopressa ® (netarsudil)

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	**NON-PREFERRED STATUS**
Central Nervous System (CNS) Agents: Parkinson's Agents	Gocovri™ (amantadine ER)
Endocrine Agents-Diabetes-Oral Hypoglycemics	Segluromet™ (ertugliflozin and metformin)
Endocrine Agents-Diabetes-Oral Hypoglycemics	Steglujan™ (ertugliflozin and sitagliptin)
Infectious Disease Agents: Antibiotics-Cephalosporins	Daxbia™ (cephalexin)
Respiratory Agents: Chronic Obstructive Pulmonary Disease	Lonhala™ Magnair™ (glycopyrrolate)
Respiratory Agents: Nasal Preparations	Xhance® (fluticasone propionate)

For additional details, the Preferred Drug List (PDL) and clinical criteria can be found at:
http://pharmacy.medicaid.ohio.gov/drug-coverage